UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,517	05/18/2000	CHARLES S. ZUKER	AURO1210-1	5179

7590 07/17/2002

LISA A HAILE
GRAY CARY WARE & FRIEDENRICH
4365 EXECUTIVE DRIVE
SUITE 1600
SAN DIEGO, CA 92121

EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1636	17

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/462,517	Applicant(s) ZUKER ET AL.	
	Examiner Q. Nguyen	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The restriction requirement dated 7/31/01 in Paper No. 11 is vacated because it was not properly restricted for the application filed as a 371 of PCT/US98/14667.

Following is a new restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2 and 9-10, drawn to a fly comprising an amino acid mutation in a transducisome protein that prevents functional binding of a signal transduction protein, wherein said amino acid mutation is not a naturally occurring mutation of inaD, and an isolated protein comprising a polypeptide of SEQ ID NO: 1 with an amino acid mutation in a PDZ domain that prevents functional binding of a signal transduction, wherein said amino acid mutation is not a naturally occurring mutation $inaD^{215}$.

Group II, claims 3-8, drawn to an isolated cell comprising a polynucleotide encoding a transducisome protein with an amino acid mutation that prevents functional binding of a signal protein, wherein said amino acid mutation is a naturally occurring mutation of inaD, and an isolated polynucleotide comprising a coding region for a transducisome protein with an amino acid mutation in a PDZ domain that prevents functional binding of a signal transduction protein, wherein said amino acid mutation is not a naturally occurring mutation $inaD^{215}$.

Group III, claims 11-13, drawn to a chimeric transducisome protein comprising at least one first PDZ domain that binds a first signal transduction protein and at least one second PDZ domain binds a second signal transduction protein, wherein said chimeric transducisome protein is not a naturally occurring protein.

Group IV, claims 14-23 and 28-29, drawn to methods of identifying modulators of signal transduction, modulators of a cell surface receptor, modulators of an ion channel, and a screening assay system for identifying modulators of transducisomes.

Group V, claims 24-27, drawn to a screening assay system for detecting protein-protein interactions using a recombinant protein comprising at least one PDZ domain, a PDZ binding protein and at least one test chemical.

Group VI, claims 30-34, drawn to an isolated, non-naturally occurring cell comprising a heterologously expressed transducisome protein comprising one or more PDZ domains and an expressed protein comprising a signal transduction protein that binds to one or more the PDZ domains; and an isolated, non-naturally occurring cell comprising a cell capable of expressing a non-naturally occurring polynucleotide comprising a coding region for a transducisome protein comprising one or more PDZ domains and a non-naturally occurring polynucleotide comprising a coding region for a heterologous protein comprising a signal transduction protein.

Group VII, claims 35-40, drawn to a chemical identified by preventing the binding of a transducisome protein with a signal transduction protein, a pharmaceutical compound comprising the chemical, and methods of treating a transducisome related disease or of modulating a signal transduction in a cell using a chemical to modulate the association of a transducisome and at least one PDZ binding protein.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I lacks unity of invention because the fly comprising an amino acid mutation in a transducisome protein and an isolated protein comprising a polypeptide of SEQ ID NO:1 with an amino acid mutation in a PDZ domain, wherein the amino acid mutation is not a naturally occurring mutation of inaD have materially different chemical structures and biological functions from an isolated cell comprising a polynucleotide encoding a transducisome protein with an amino acid mutation, wherein the amino acid mutation is a naturally occurring mutation of inaD of Group II, a chimeric transducisome protein of Group III, a screening assay system for detecting protein-protein interactions

of Group IV, an isolated, non-naturally occurring cell of Group VI and an identified chemical that prevents the binding of a transducisome protein with a signal transduction protein of Group VII. The methods of Groups IV and VI are materially different and plurally independent from each other because each is practiced with materially different process steps, the process steps are the special technical features which distinguisch each method from the other. As such, the methods for identifying modulators of signal transduction using a cell-based assay of Group IV require different starting materials, steps as well as different technical considerations from methods of treating a transducisome related disease or of modulating a signal transduction in a cell using an identified chemical.

Additionally, PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups IV and VI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group VI is an isolated, non-naturally occurring cell containing a heterologously expressed transducisome protein or a non-naturally occurring polynucleotide coding for a transducisome comprising one or more PDZ domains with an expressed protein comprising a signal transduction protein that binds to one or more PDZ domains or a non-naturally occurring polynucleotide encoding a heterologous protein comprising a signal transduction protein, which is shown by Huganir et al. (U.S. Patent No. 6,001,575 with the effective filing date of 5/19/1997) to lack novelty or inventive step. Huganir et al. teach the preparation of HEK-293 cells

transfected with a cDNA encoding the 4th, 5 th and 6th PDZ domains of GRIP and a cDNA encoding the full-length of either GluR2 subunit or GluR3 subunit of an AMPA receptor that can interact with the PDZ domains of GRIP or a cDNA encoding various C-terminal mutants of the GluR2 subunits (see example 4). Huganir et al. further teach screening drugs to identify drugs which specifically interact with, bind to, and or modify the physiological effects of GRIP or GRIP2 (col. 8, lines 22-24). Moreover, at the effective filing date of the present application, Saras et al. (TIBS 21:455-458, 1996) teach that PDZ domains have been identified in a variety of proteins that are often found in structures at the plasma membrane and are involved in signal transduction pathways, including the inaD protein which has five PDZ domains and function as an adaptor molecule to promote connections between different molecules such as TRP (a Ca channel), NorpA (phospholipase C) and InaC (ePKC) involved in a Drosophila vision G-protein coupled phospholipase C-mediated signaling pathway as evidenced by the teaching of Huber et al. (EMBO J. 15:7036-7045, 1996). Additionally, at the effective filing date of the present application, a signal transduction detection system in a cell has been taught by Negulescu et al. (U.S. Patent No. 6,004,808 with the effective filing date of 6/21/1996). Accordingly, the special technical feature of Group VI does not make a contribution over the prior art.

Should Group III be elected, a further election of species is required.

Claims 11, 12 and 13 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named first signal transduction protein listed in the Markush group of claim 12: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

A specifically named second signal transduction protein listed in the Markush group of claim 13: PKC, TRP or PLCbeta.

Should Group IV be elected, a further election of species is required.

Claims 14-23 and 28-29 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named signal listed in the Markush group of claims 19: a chemical signal found in blood, a chemical signal found in a synaptic cleft, a chemical signal found in interstitial fluid, a chemical signal found in air and light.

A specifically named signal transduction protein listed in the Markush group of claims 20: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

Should Group V be elected, a further election of species is required.

Claims 24-27 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named PDZ binding protein listed in the Markush group of claim 26: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

Should Group VI be elected, a further election of species is required.

Claims 31-34 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named signal transduction protein listed in the Markush group of claims 32: a kinase, a phosphatase, a GPCR, a tyrosine kinase receptor, a tyrosine phosphatase receptor, an ion channel, a G-protein, a phospholipase, or a calcium binding protein.

Should Group VII be elected, a further election of species is required.

Claims 38-39 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named signal transduction listed in the Markush group of claims 39: G-protein coupled, ion channels, kinases and phospholipases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600